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S. S. S.  
S. S. S.

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PATENT

## SYSTEM TO FORM, FILL AND SEAL FLEXIBLE BAGS

### Related Applications

This Application is a continuation of International Application No. PCT/IB97/01458, filed November 18, 1997. International Application No. PCT/IB97/01458 is hereby incorporated herein by reference, and made a part hereof.

### Technical Field

The present invention concerns a system to form, fill and seal (F.F.S.) containers of flexible plastic materials, in particular sterilizable bags containing solutions for the administration of infusion solutions.

### Background of The Invention

Numerous prior art systems for manufacturing flexible containers, or bags, for use with infusion solutions in the medical field are known. For example, U.S. Patent No. 4,456,813, describes a system for industrial production of these types of bags. These bags are sometimes generally referred to as form, fill and seal (F.F.S.) containers. These bags typically have a laminated construction and include a valve to accommodate various connectors of an infusion apparatus, such as a luer-type valve. The bags are typically sterilized during or after the manufacturing process. Sterilization of a bag that incorporates various design features, such as valves, can be difficult. The manufacturing and sterilizing process becomes even more difficult with present day bags that may be required to have additional features, such as means for bag suspension, complex valves, or twin-valve systems. These features create areas of the bag that are difficult to access by a sterilization solution during the sterilization process. This can cause variation in the sterilization times of these areas, which in

turn can cause incomplete or ineffective sterilization. This variation can also have an effect on the proper selection of sterilization solution dosages.

Therefore, it is an object of the present invention to provide a system and associated method for manufacturing F.F.S. containers of flexible plastic materials that can be easily sterilized without the disadvantages of previous systems and methods.

It is also an object of the present invention to provide a system and method for manufacturing F.F.S. containers of flexible plastic materials that are characterized by high manufacturing efficiency, sterilization reliability, and precision.

It is a further object of the present invention to provide a less expensive and space-efficient system for manufacturing F.F.S. containers of flexible plastic materials.

These and other objects will become readily apparent after review of the specification, drawings, and accompanying claims.

#### **Summary of the Invention**

The system of the present invention includes a method of manufacturing form, fill and seal (F.F.S.) containers, or bags, made from flexible plastic materials. The system and associated method generally include the steps of: (1) feeding from at least one reel a plastic and flexible material in the form of a film or pellicle, preferably multilayer, for forming the bag; (2) printing the material pulled from the reel; (3) winding the printed material; (4) washing the printed material; (5) aligning and folding the printed and washed film; (6) welding the folded film in a first direction; (7) feeding and applying valves on the surface of the folded and welded film; (8) making a second welding in a second direction; and, (9) cooling and cutting the bags to send to them for overwrapping and sterilizing.

#### **Brief Description of the Drawings**

FIG. 1 is a block diagram of the system of the present invention.

FIG. 2 is a schematic diagram of an embodiment of the system of FIG. 1.

FIG. 2A is a partial view of a variation of the embodiment disclosed in FIG.

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FIG. 2B is a partial perspective view of an embodiment of a dry cleaning means of the present invention.

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FIG. 2C is a partial perspective view of the embodiment of the dry cleaning means of FIG. 2B.

FIG. 3 is a perspective view of a schematic representation of a preferred embodiment of the system of FIG. 1.

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FIG. 4 is an elevational view, partially in section, of a first embodiment of a two-valve structure of a bag manufactured according to the method of the present invention.

FIG. 5 is an elevational view, partially in section, of a second embodiment of a two-valve structure of a bag manufactured according to the method of the present invention.

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FIG. 6 is a top plan view of a bag manufactured according to the method of the present invention and incorporating the valve assembly of FIG. 4.

FIG. 7 is a top plan view of a bag manufactured according to the method of the present invention and incorporating the valve assembly of FIG. 5.

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FIG. 8 is a schematic view in partial cross-section of a humidification means for humidifying the valves of the bags manufactured according to the method of the present invention.

FIG. 9 is a schematic view of a high precision liquid dosing means for filling the bags manufactured according to the method of the present invention.

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FIG. 10 is a schematic view of a filling portion of an actuating machine of the system of the present invention that incorporates the dosing means of FIG. 9.

FIG. 11 is an elevational side view of an embodiment of a total print station of the system of the present invention.

FIG. 12 is a perspective view of a valve welding station of the system of the present invention.

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FIG. 13 is a perspective view of a final welding and molding block of the

system of the present invention.

### **Détail Description of the Preferred Embodiments**

5 The system of the present invention is represented in FIGS. 1 and 2. The system comprises at least five stations, each involving one or more steps of the method of the present invention.

10 Referring to FIG. 1, block 1 represents the supplying station that feeds a film F from a first reel B. The dashed line rectangles B' and B" represent optional reel configurations. The reel B' can be placed in addition to and parallel to the first reel B. The reel B' is preferably of the same width as the first reel B. Alternatively, the reel B" can be used in lieu of reels B or B'. In this case, the reel B" is preferably n times the width of B or B'. Referring to FIG. 2, a tension adjustment and braking mechanism DF is provided in communication with the reels B and/or B', or B".

15 Block 2 of FIG. 1 represents a total printing (TP) station 2a that is followed by an accumulation station 2b. The TP station 2a provides in-line printing of the film. The accumulation station 2b accumulates the printed film in-line with the TP station 2a. The TP station 2a includes a hot printer that utilizes a hot press and a pigmented film to imprint characters on the film. The characters of the printed matter are on a cliché of the hot printer. The TP station 2a is preset to obtain the character printing information, such as a prescription, a lot number, or data relating to the production. Furthermore, a print menu incorporated into the TP station 2a allows for the setup of various printing parameters, such as bag size (50cc to 5,000cc), temperature, speed, and the like.

25 Block 3 of FIG. 1 represents a washing station phase that comprises a single dry washing stage. The film entering the dry washing stage is labeled FST and the film exiting the dry washing stage is labeled FSTL, as shown in FIG. 1. The dry washing stage does not allow the film to contact any liquids or supports of the system. A preferred embodiment of the washing stage is represented in FIGS. 2B and 2C. In this embodiment, the washing stage is formed by two superimposed chambers 101 and 102 forming a central slot for the printed film FST to pass therethrough. The printed

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film FST is suspended and subjected to filtered air AF flowing from three nozzles 103, 104 and 105. The air flows over the printed film FST and carries away any particles or impurities from the printed film FST. The air flows out through nozzles 106, 107 and 108. The stations represented by blocks 2 and 3 can operate and handle a plurality of film configurations, such as in the case of using two reels B and B' of equal length, or using a single reel B" having a width n times greater than B or B'.

Block 4 of FIG. 1 represents a station comprising four substeps for handling the printed and dry washed film FSTL. The four substeps comprise accumulation 4b, gimballing alignment 4d, folding 4e, and towing 4f. Compared to prior art systems, a drying phase is not needed because dry washing is utilized. Furthermore, a sterilization step that utilizes ultraviolet radiation has also been eliminated.

Referring to FIG. 2, the printed and dry washed film FSTL is first aligned by alignment rollers 4b. First and second folding rollers 4e and 4e' facilitate a folding prism PR therebetween for folding the printed and dry washed film FSTL. A towing roller 4f cooperates with the second folding roller 4e' to complete the handling station.

Block 5 of FIG. 1 represents the bag formation step of the manufacturing process. The bag formation step involves vertical welding of the film as well as the attachment of one or more valves. The bag formation step comprises a vertical welding substation 5a and a valve attachment substation 5b. The bag is formed and the valves are attached by welding. FIGS. 4 and 5 show two valve structures that can be attached to the bag. Such valves are disclosed in U.S. Patent No. 4,467,003.

In more detail, the bag formation step of block 5 comprises a vibrator 5b1 for feeding the valves during the assembly process, a humidification means, such as a spray wetter 5b2, for wetting the valve cavities, a detection and controlling means 5b3 for the spray wetter, a suspension hole forming means 5c that forms a suspension hole in the bag, and a suspension ring application means 5f that applies suspension rings to the suspension hole of the bag. A vibrator 5f1 is also included for feeding the suspension rings during the assembly process.

In a preferred embodiment of the invention, the valve welder is an ultrasound welder with open ring control of position and approach speed. Fig. 12 shows the

valve attachment station 5b as a welding and molding station. The valve attachment station 5b comprises a position transducer 81, a cylinder 82, a slide 83, a sonotrode 84 (welding head) and a transducer 85. The system allows for continuous checking of the position and speed of the sonotrode 84 at substation 5b with respect to an anvil (not shown). With a PID (Proportional Integral Derivative) algorithm sampled to a thousandth of a second, the speed and acceleration/deceleration of the sonotrode/anvil impact was optimized. This allows the welding operation and the resulting weld to be optimized with respect to the bag material utilized.

Referring to FIG. 1, station SP fills the bag with the proper dose, or volume, of the liquid RIEM. The station SP is a precise, substantially automatic station that includes electropneumatic valves 60 and 62 that are fed by line 61. A processing switchboard 63 allows for control of the valves 60 and 62. The valves 60 and 62 provide a double electropneumatic thrust and permit opening and closing of the valves 60 and 62 in a time of 3 to 5 thousandths of a second, which provides a dosage tolerance of +/- 1 cc per dosage quantity.

In a preferred embodiment, the valves 60 and 62 are controlled by pulses generated by a lobed flowmeter that utilizes a Hall effect. Figs. 9 and 10 depict the station SP in more detail.

FIG. 13 depicts a mechanism for shaping the bags contemporaneously with horizontal welding via movable bars 71 and 73. The bars 71 and 73 are heated by electric heating elements and allows the bars 71 and 73 to compress and thermoform the bags without the formation of ears. The mechanism of FIG. 13 also includes a non-heated cutting edge 72 and a cutting edge support 74.

A PID type algorithm is used to control the temperature of the bars 71 and 73. For example, the temperature can be controlled on twelve selected points on the bars 71 and 73. The non-heated bars 72 and 74 provide immediate cooling of the thermoformed area of the bag. The bars 72 and 74 also cut the bags to the desired dimension.

The valve cavities depicted in FIGS. 4 and 5 can be humidified, or wetted, by use of the mechanism depicted in FIG. 8. The mechanism includes a valve VS, a

fluxstate FLU, a nebulization nozzle US, a piston PM to move the nozzle US, a sensor SEP that controls the piston PM, a bridging circuit for the measurement of the electrical conductivity in the wetted cavity that provides humidification control, and a discharge channel for the wetting liquid CSLB. The nozzle US includes a lance for penetration into the valve cavities. The wetting liquid CSLB is preferably distilled water, a physiological solution, or hydrogen peroxide. The wetting liquid is used to sanitize and detect electric conductability in the cavities.

The system of the present invention can be used to weld one or more valves onto the same bag or even welding valves only on a particular series of bags, e.g., even or odd numbered bags. The film F in FIG. 1 used to form the bags can be multilayer, comprising polymers or copolymers that include laminated olefins, amides, esters, or the like, as disclosed in U.S. Patent Number 4,326,574. Preferably, the film F is coextruded, such as disclosed in Applicant's European Patent Application Number 0658421 and International Patent Number WO 95/16565.

Optimal results have been obtained with coextruded film based on two external layers of ethylene and propylene copolymers or of two chemically diverse layers, such as polyethylene/polypropylene. The adhesion of the two layers is ensured by an appropriate coextruded binding, which is also a polyolefin. By choosing the appropriate composition of the external layers, the binding and the adhesion of the layers can be optimized with respect to weld temperatures and weld resistance during manufacturing. Various properties of the bag material may also be optimized, such as strength of the bag and bag weld, transparency, sterilizability, etc. The coextruded films can also have additional layers that are themselves coextruded or laminated to the coextruded films.

While the specific embodiments have been illustrated and described, numerous modifications come to mind without significantly departing from the spirit of the invention and the scope of protection is only limited by the scope of the accompanying Claims.